

Accessing Package Insert Information (Content of Labeling in SPL Format) Via Mobile Devices

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Overview

- SPL Standard
- Exchange of SPL Data
- Accessing SPL Data Via Mobile Devices

Many Uses of Cell Phones/ Tablet Computers



- Video conference w/friends and family
- Remotely control home lights/appliances, etc...
- Scan checks/Pay bills
- Watch TV shows/movies
- Play video games
- Use Apps
- View SPL Data?

SPL Standard

- HL7 health and regulatory data international standard
- Adopted by FDA
- Extensible Markup Language (XML)
- Exchange of product and facility information
- Current use at FDA:
 - Initiative to improve patient safety through better access to product information
 - Drug product information (Rx and OTC human and animal drug products)
 - Drug establishment registration

Indexed SPL Data

- Indexed clinical data (e.g. pharmacologic class, indications)
 - Inserted machine readable tags not in printed content of labeling
 - Allows users to rapidly search and sort information
 - Support automated health information systems
 - Electronic health records, electronic prescribing, clinical decision support systems

Multiple Purposes for SPL File

- One Content of Labeling SPL File – Companies may fulfill multiple regulatory obligations and other goals
 - Content of labeling (compliance with Electronic Labeling Rule)
 - Drug Listing (compliance with FDAAA 2007)
 - Electronic label published in public repository
 - Downloaded into healthcare information systems

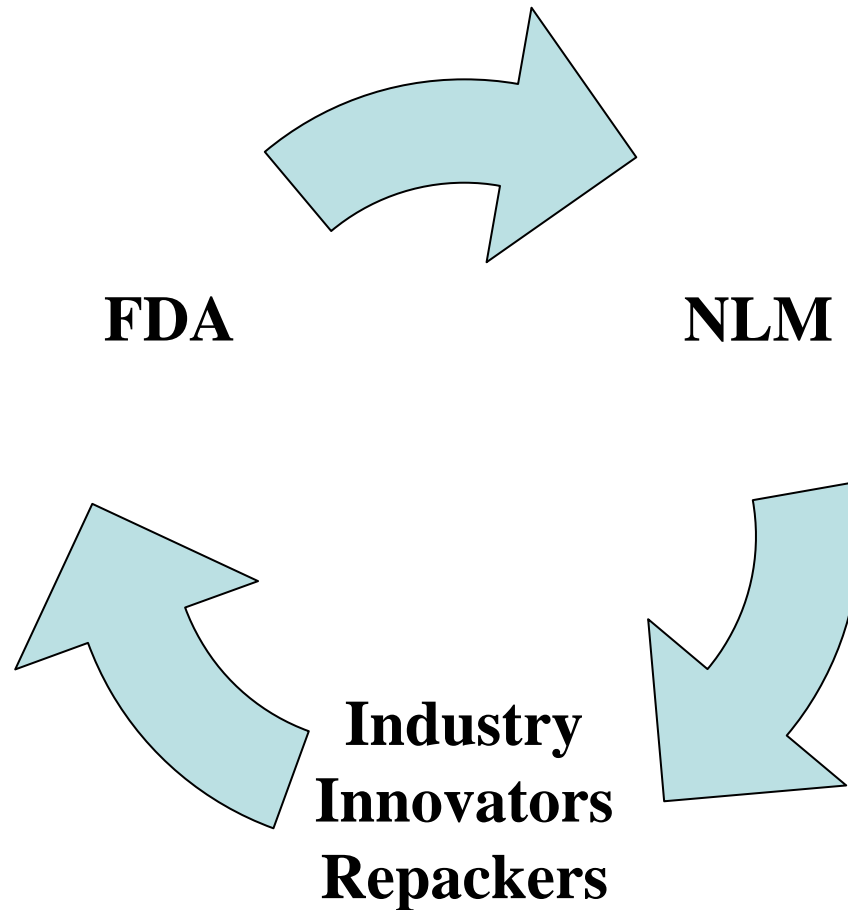
Another Purpose – SPL as Data Source for Mobile Devices



- Why not for viewing content of labeling?
- Patients, pharmacists, doctors, nurses, etc... have cell phones and tablet computers
- Data source for medical information mobile device apps.

Exchanging SPL Data

Exchanging SPL Data



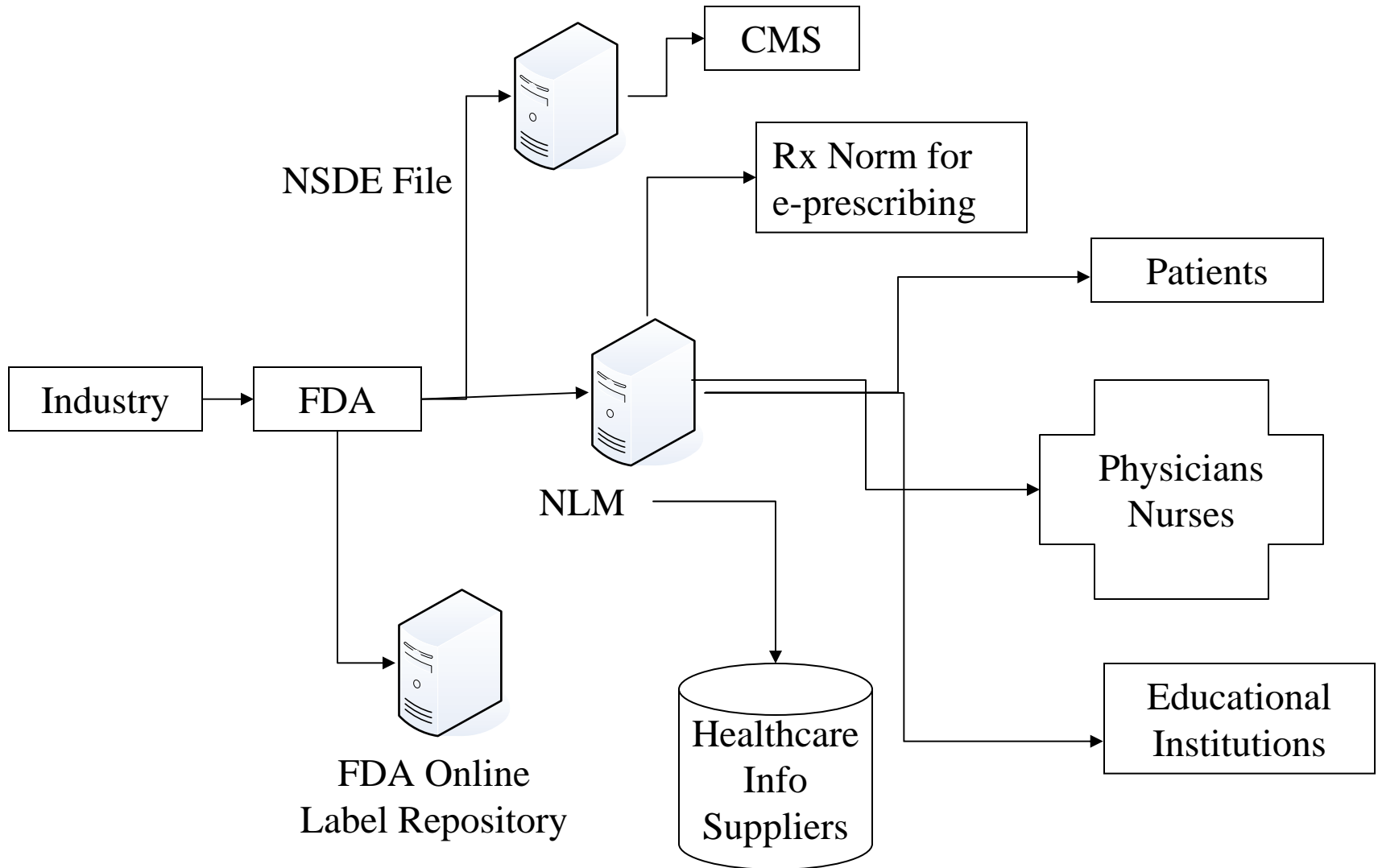
Types of SPL Product Data Exchanged

- Drug Products
 - Human Rx Drugs
 - Approved & Unapproved Rx drugs
 - Unapproved medical gases
 - Unapproved homeopathic
 - Human OTC Drugs
 - OTC monograph final
 - OTC monograph not final
 - OTC homeopathic
 - Animal Rx drugs
 - Approved Rx
 - Unapproved Rx
 - Animal OTC Drugs
- Other Products
 - Medical device (content of labeling) (Voluntary submissions only)
 - Medical foods (Voluntary submissions only)
 - Dietary Supplements (Voluntary submissions only)

Components of Exchanged SPL Files

- Components
 - Content of labeling (e.g. package inserts, drug facts)
 - Product data elements
 - Images (chemical structures, graphs, products)

Data Sharing



Same Business Day Posting of SPL Files

- SPL files can be posted on DailyMed and labels.fda.gov same business day submitted
- Submit before 11:00 a.m., ET
- Eligible SPL files which pass technical validation can be posted same business day



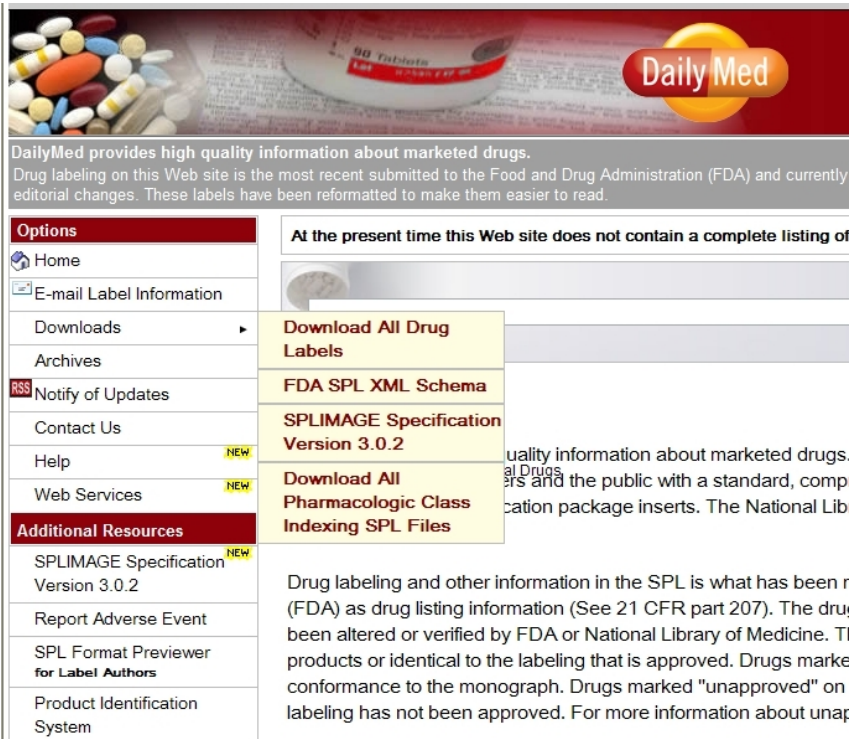
Why Post Same Package Insert Info Twice – DailyMed Permanent Link

- Posting of copies of electronic content of labeling on company website AND DailyMed?
- DailyMed permanent link – Place link on company website
 - SPL file updated on DailyMed – SPL file updated on company website
- <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=“enter your SPL file’s set ID here”>

Accessing SPL Data Via Mobile Devices

DailyMed

- FDA-to-NLM - Daily transmissions of up-to-date product information received from drug companies
- MOU (FDA/NLM)
- NLM makes SPL files available via download



The image shows a screenshot of the DailyMed website. The header features a banner with various pills and a 'DailyMed' logo. Below the banner, a text box states: 'DailyMed provides high quality information about marketed drugs. Drug labeling on this Web site is the most recent submitted to the Food and Drug Administration (FDA) and currently editorial changes. These labels have been reformatted to make them easier to read.' The main navigation menu is on the left, with sections for 'Options' and 'Additional Resources'. The 'Options' section includes links for Home, E-mail Label Information, Downloads, Archives, Notify of Updates, Contact Us, Help, and Web Services. The 'Additional Resources' section includes links for SPLIMAGE Specification Version 3.0.2, Report Adverse Event, SPL Format Previewer for Label Authors, and Product Identification System. A dropdown menu is open under 'Downloads', showing links for 'Download All Drug Labels', 'FDA SPL XML Schema', 'SPLIMAGE Specification Version 3.0.2', and 'Download All Pharmacologic Class Indexing SPL Files'. A message box at the top right states: 'At the present time this Web site does not contain a complete listing of'.

DailyMed provides high quality information about marketed drugs.
Drug labeling on this Web site is the most recent submitted to the Food and Drug Administration (FDA) and currently editorial changes. These labels have been reformatted to make them easier to read.

At the present time this Web site does not contain a complete listing of

Options

- Home
- E-mail Label Information
- Downloads
- Archives
- Notify of Updates
- Contact Us
- Help
- Web Services

Additional Resources

- SPLIMAGE Specification Version 3.0.2
- Report Adverse Event
- SPL Format Previewer for Label Authors
- Product Identification System

Download All Drug Labels


FDA SPL XML Schema

SPLIMAGE Specification Version 3.0.2

Download All Pharmacologic Class Indexing SPL Files

Drug labeling and other information in the SPL is what has been r (FDA) as drug listing information (See 21 CFR part 207). The dru been altered or verified by FDA or National Library of Medicine. TI products or identical to the labeling that is approved. Drugs marke conformance to the monograph. Drugs marked "unapproved" on labeling has not been approved. For more information about unap

DailyMed Mobile



Search:

Limit:

| | | | |
|------|-----|-------|-------|
| DRUG | NDC | CLASS | SETID |
|------|-----|-------|-------|

Label Type:

| | |
|-------|--------|
| HUMAN | ANIMAL |
|-------|--------|

GO

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U.S. National Library of Medicine
National Institutes of Health
Department of Health & Human Services

[Visit the Full DailyMed Site](#)
(not optimized for mobile devices)


- NLM's version of their DailyMed website optimized for mobile devices

DailyMed Mobile

Content of Labeling




CYMBALTA (duloxetine hydrochloride) capsule, delayed release
[Eli Lilly and Company]


 HIGHLIGHTS OF PRESCRIBING INFORMATION

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Cymbalta or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Cymbalta is not approved for use in pediatric patients [see *Warnings and Precautions* (5.1), *Use in Specific Populations* (8.4), and *Information for Patients* (17.2)].

 1 INDICATIONS AND USAGE

 2 DOSAGE AND ADMINISTRATION

 3 DOSAGE FORMS AND STRENGTHS

- Mobile version of DailyMed – permits expansion of certain sections of labeling instead of all at once.

DailyMed Mobile

Image of Container Label



- Permits users to view updated representative samples of carton/container label

DailyMed Mobile RxNorm (ePrescribing)

| RxNorm | |
|---|--------|
| RXNORM NAMES | RXCUI |
| Cymbalta 20 MG (duloxetine hydrochloride 22.4 MG) Enteric Coated Capsule | 596928 |
| Cymbalta 20 MG Enteric Coated Capsule | 596928 |
| duloxetine 20 MG (duloxetine HCl 22.4 MG) Delayed Release Capsule | 596926 |
| Cymbalta 60 MG (duloxetine hydrochloride 67.3 MG) Enteric Coated Capsule | 615186 |
| duloxetine 60 MG (duloxetine hydrochloride 67.3 MG) Delayed Release Capsule | 596934 |
| Cymbalta 30 MG (duloxetine hydrochloride 33.7 MG) Enteric Coated Capsule | 596932 |
| Cymbalta 30 MG Enteric Coated Capsule | 596932 |

- View RxNorm names and codes for products

DailyMed Mobile

Structured Product Data Elements

CYMBALTA

duloxetine hydrochloride capsule, delayed release

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:0002-3235 |
| Route of Administration | ORAL | DEA Schedule | |

Active Ingredient/Active Moiety

| | | |
|--|-------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
| Duloxetine hydrochloride (Duloxetine) | Duloxetine | 20 mg |

Inactive Ingredients

| | |
|-----------------|----------|
| Ingredient Name | Strength |
|-----------------|----------|

Gelatin

Hypromelloses

HYPROMELLOSE ACETATE SUCCINATE 16070722 (3 MM2/S)

Sodium lauryl sulfate

Sucrose

Talc

Titanium dioxide

Triethyl citrate

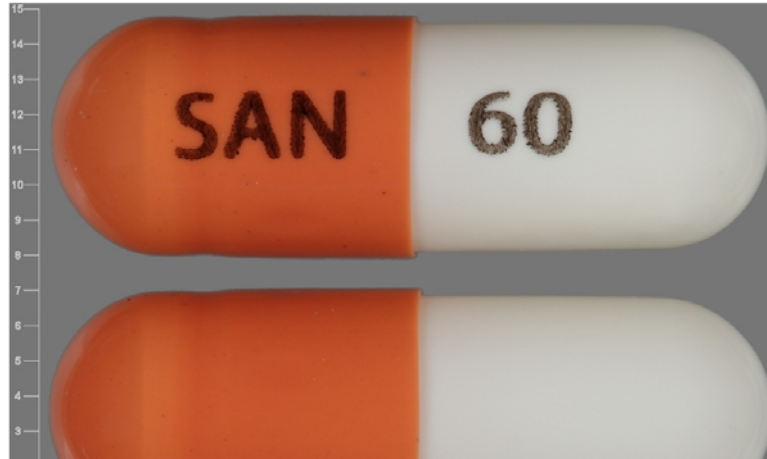
FD&C BLUE NO. 2

FERRIC OXIDE YELLOW

Product Characteristics

| | | | |
|-------|----------------------|-------|----------|
| Color | green (opaque green) | Score | no score |
| Shape | CAPSULE | Size | 15mm |

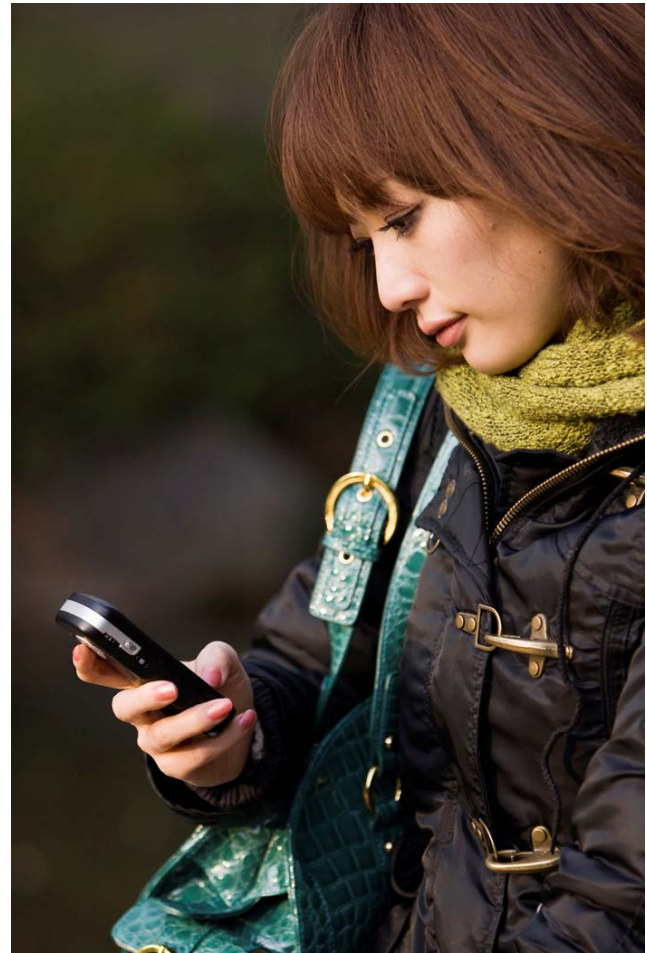
DailyMed Mobile Product Image



- Companies may now voluntarily provide images of their solid oral dosage form products via SPL files.
- Identification of products by consumers or poison control centers.

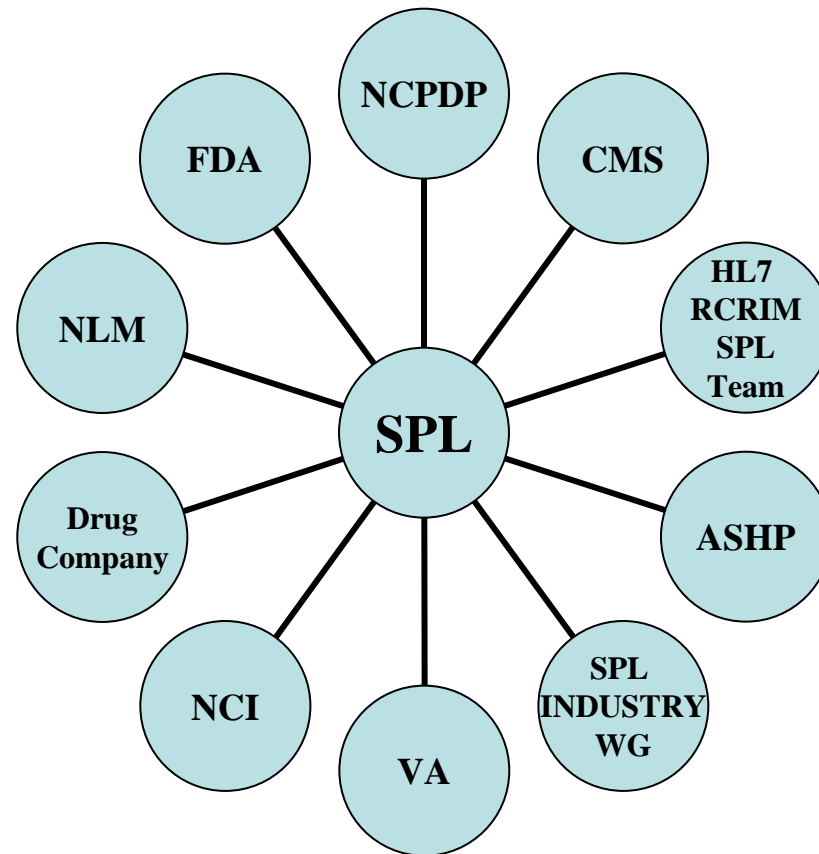
Consumers: Access to Up-to-Date Drug Product Information

- Access to same package insert info available to healthcare professionals
- Can review labels while awaiting filling of prescription.
- Updated medication guides, etc...
- Access to updated drug facts labels for OTC drug products



Other SPL-related Topics

Collaboration = SPL Success



Accomplishments

- FDA has been using the SPL standard for over 6 years
- DailyMed –
 - **October 2012** – over **10 million** visits per month
- Unique SPL documents posted on DailyMed
 - **October 2012** – over **42,000**

Stay Informed

- FDA Data Standards Council website listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is a blue header for the U.S. Department of Health & Human Services with the website address www.hhs.gov. Below this is the FDA logo and the text "U.S. Food and Drug Administration". A navigation bar contains links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. A search bar and an "A-Z Index" link are also present. The main content area is titled "For Industry" and includes a breadcrumb trail: Home > For Industry > Data Standards. On the left is a sidebar with a "Data Standards" menu containing links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled "FDA Resources for Standards" and features a sign-up link for email updates, a paragraph describing the council's role, and a link to "Structured Product Labeling".

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

Sign up for email updates.

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

Structured Product Labeling

SPL-related Questions

- SPL e-mail account (spl@fda.hhs.gov)

Thank You